DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; (S)-methoprene

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Wellmark International. The NADA provides for oral use of (S)-methoprene for the prevention and control of flea populations.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540.

SUPPLEMENTARY INFORMATION: Wellmark International, 1000 Tower Rd., suite 245, Bensenville, IL 60106, filed NADA 141–162 that provides for use in dogs, 9 weeks of age and older and 4 pounds body weight or greater, for the prevention and control of flea populations. (S)-methoprene prevents and controls flea populations by preventing the development of flea eggs but does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas. NADA 141–162 is approved as of January 24, 2000, and the regulations are amended in 21 CFR part 520 by adding new § 520.1390 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support

approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning January 24, 2000, because no active ingredient (including any ester or salt of the drug) has been previously approved in any other application filed under section 512(b)(1) of the act.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for "Wellmark International" and in the table in paragraph (c)(2) by numerically adding an entry for "011536" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * *	* * *
Wellmark International, 1000 Tower Rd., suite 245, Bensenville, IL 60106	011536
* * * *	* * *

(2) * * *

Drug labeler code	Firm name and address
* * * *	* * *
011536	Wellmark International, 1000 Tower Rd., suite 245, Bensenville, IL 60106
* * * *	* * *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

4. Section 520.1390 is added to read as follows:

§ 520.1390 (S)-methoprene.

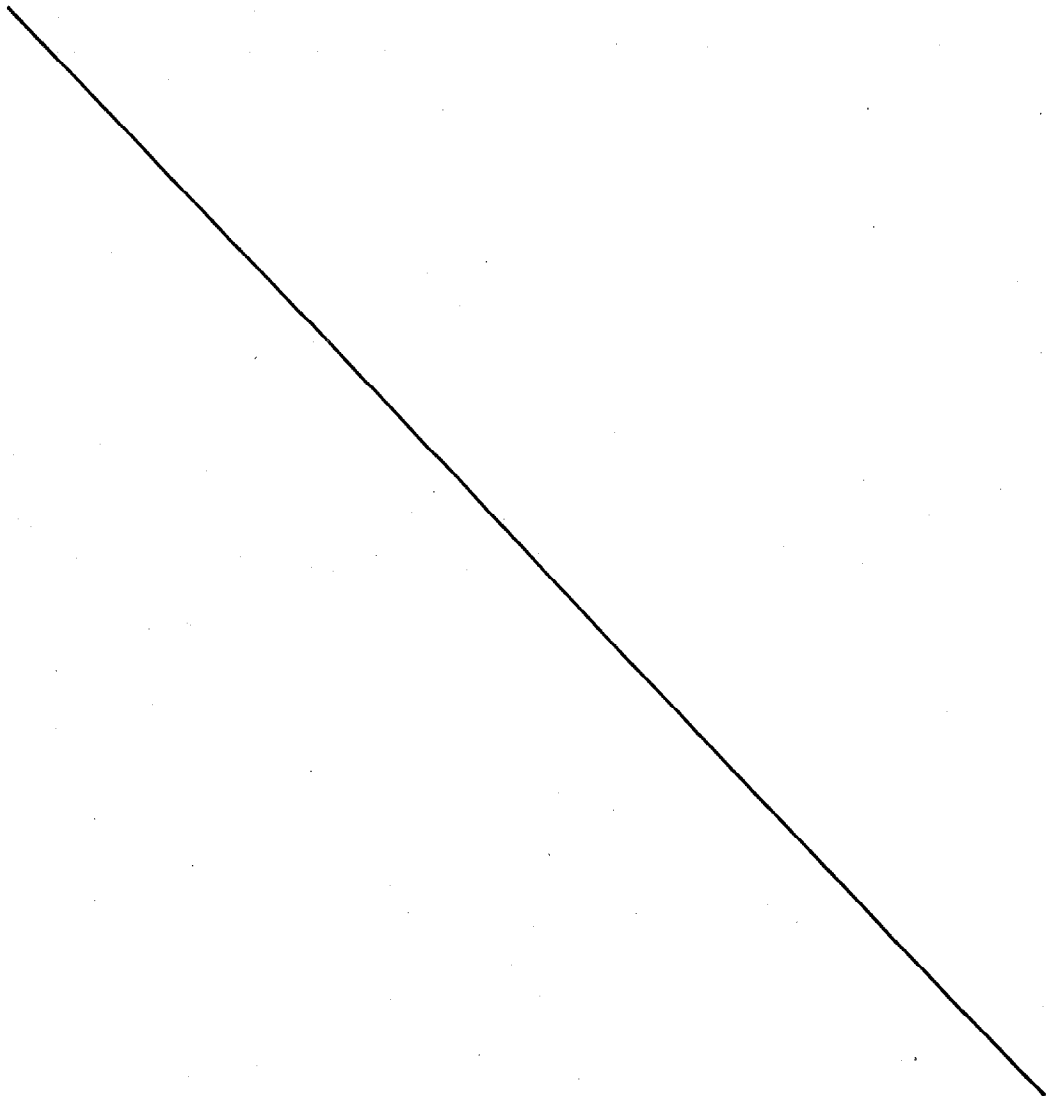
(a) *Specifications.* Each capsule contains 154, 308, or 462 milligrams (mg) of (S)-methoprene.

(b) *Sponsor.* See No. 011536 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount*. Capsules are given orally, once per week at the recommended minimum dosage of 10 mg of (S)-methoprene per pound of body weight (22 mg/ kilograms).

(2) *Indications for use*. For oral use in dogs, 9 weeks of age and older and 4 pounds body weight or greater, for the prevention and control of flea populations. (S)-methoprene prevents and



controls flea populations by preventing the development of flea eggs ~~and~~ but does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

Dated: 3/20/00
March 20, 2000

SFS

Stephen F. Sundlof
Director
Center for Veterinary Medicine

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Michael W. Bell